MAY 1 6 2002

K020562

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510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
APEX Intramedullary Nail System

Submission Information

Name and Address of the Sponsor Of the 510(k) Submission:	Magly Orthopedics, LLC 14241 NE Woodinville-Duvall Road, #415 Woodinville, Washington 98072 425.489.2057 Phone 425.482.0147 Fax
Contact Person:	Dave Stinson
Date Summary Prepared:	February 2, 2002

Device Identification

Proprietary Name:	APEX Intramedullary Nail System
Common Name:	Intramedullary Fixation System
Classification:	Intramedullary Fixation Rod 21 CFR §888.3020

Predicate Device Identification

The design and function of the APEX Intramedullary Nail System is substantially equivalent to that of the predicate *Stryker Howmedica Osteonics* Retrograde/Antegrade Femoral Nail, the predicate *ACE* AIM Titanium Nails (*DePuy/ACE, a Johnson & Johnson Company*), and the *Smith & Nephew* TriGen Knee Nail. The APEX Intramedullary Nail System is similar to the listed predicate device in design, function, materials used, and indications for use.

Device Description

The APEX Intramedullary Nail System consists of intramedullary rods for fixation inside the canal of the tibia or femur. All the rods are cannulated and cylindrical in shape. The rods are available in a variety of diameters and lengths and have holes located the proximal and distal ends for fixation to bone by means of locking screws. An end cap is available. It screws into the threaded end of the nails to prevent bone ingrowth, which may hamper attachment of the extraction instrumentation.

All components of the APEX Intramedullary Nail System are manufactured from titanium alloy (Ti-6Al-4V).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Magly Orthopedics, LLC
c/o Mr. Dave Stinson
15009 NE 195th Street
Woodinville, WA 98072

Re: K020562
Trade/Device Name: APEX Intramedullary Nail System
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 15, 2002
Received: February 20, 2002

Dear Mr. Stinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement of Indications for Use

510(k) Number: ~~Pending~~ K020562

Device Name: APEX Intramedullary Nail System

Indication(s) for Use:

- Low subtrochanteric fractures
- Pseudarthrosis and corrective osteotomies
- Transverse fractures
- Pathologic fractures, impending pathologic fractures, and tumor resections.
- Oblique and spiral fractures
- Supracondylar fractures, including those with intra-articular extension
- Segmental fractures
- Ipsilateral femoral neck fractures
- Comminuted fractures
- Fractures proximal to total knee arthoplasty
- Fractures with bone loss
- Fractures distal to a hip implant
- Nonunions and malunions.
- Acute bone lengthening and shortening
- Reamed and unreamed applications
- High Supracondylar fractures, including those with intra-articular extension.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020562

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)